

REMARKS

Claims 1 through 14 have been rejected by the Examiner. Claim 1 has been amended to incorporate the limitations present in claims 4 and 5, now canceled. Claims 1 through 3 and 6 through 14 are pending.

Rejections under 35 U.S.C. §102:

Claim 1 has been rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by Pyles U.S. Patent No. 5,669,882. Applicant respectfully traverses this rejection.

The Examiner argues that Pyles teaches every feature present in Applicant's claim 1. In order for a claim to be anticipated under 35 U.S.C. §102, a single prior art reference must disclose each and every element of the claimed invention. Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715, 223 U.S.P.Q. 1264, 1270 (Fed. Cir. 1984). If the reference fails to suggest even one limitation of the claimed invention, the claim is not anticipated. Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1574, 224 U.S.P.Q. 409,411 (Fed. Cir. 1984).

The Examiner has failed to present a single prior art reference that anticipates Applicant's claimed invention. Specifically, Applicant has amended claim 1 to recite the structural feature of viewable indicia of former claims 4 and 5, now canceled. Because each and every element present in Applicant's claim 1 is not present in Pyles as a single disclosure, claim 1 cannot be said to be anticipated by Pyles.

Claim 1 is not anticipated by Pyles within the proper meaning of 35 U.S.C. §102(b). This rejection should, therefore, be withdrawn.

Claims 1, 4 through 6, 9 through 11 have been rejected by the Examiner under 35 U.S.C. 102(e) as being anticipated by Zohmann U.S. Patent No. 6,558,353. Applicant respectfully traverses this rejection.

In order for a claim to be anticipated under 35 U.S.C. §102, a single prior art reference must disclose each and every element of the claimed invention. Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715, 223 U.S.P.Q. 1264, 1270 (Fed. Cir. 1984). If the reference fails to suggest even one limitation of the claimed invention, the claim is not anticipated. Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1574, 224 U.S.P.Q. 409,411 (Fed. Cir. 1984).

Zohmann fails to teach the bone marrow aspiration device defined by independent claim 1 and fails to teach a biopsy system defined by independent claim 6. As to the claimed features required by Applicant's claim 1, the device taught by Zohmann is a spinal needle – not a bone marrow aspiration device.

Furthermore, the needle of Zohmann is absent the single laterally oriented distal opening *immediately adjacent* to the distal tip required by Applicant's claims 1 and 6. The Examiner alleges this is present in Zohmann. On the contrary, Zohmann teaches a lateral opening located at a *proximal distance* to the distal tip. Even further, Zohmann is absent an arcuate curved surface terminating at the distal-most point of the distal opening as required by Applicant's claims. These limitations are depicted in Applicant's figures as well.

Finally, the Examiner has simply fabricated that Zohmann discloses "a biopsy system capable of obtaining a bone marrow sample". No such teaching or suggestion appears in Zohmann.

Given the above, the claims are not anticipated by Zohmann within the proper meaning of 35 U.S.C. §102. This rejection should, therefore, be withdrawn.

Rejections under 35 U.S.C. §103:

Claims 1 through 3, 6 through 8 and 11 have been rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Krueger et al. U.S. Patent No. 6,478,751 in view of Pyles U.S. Patent No. 5,669,882. The Examiner maintains this rejection, and Applicant respectfully continues to traverse this rejection for the following reasons.

The Examiner argues that Krueger et al. disclose a bone biopsy system containing most of Applicant's claimed components, but that Krueger fails to teach the arcuate distal tip terminating at the distal-most point of the laterally oriented opening. The Examiner relies upon Pyles for a teaching of a needle structure with such a tip structure, concluding that one of ordinary skill in the art would have found the modification of Applicant's system to have the Pyles needle structure to be obvious. The Examiner likewise applies his arguments against Applicant's method claims citing Krueger for several method steps in Applicant's method claim 12.

Applicant's invention pertains to an improvement to the Krueger '751 system. In addition to the Pyles spinal epidural needle being in an unrelated field and context to Applicant's bone biopsy system, it is still not understood why one of ordinary skill in the art would have modified the Krueger aspiration needle component to contain the tip configuration of a spinal epidural needle. Spinal epidural needles are not used to penetrate bone to collect bone marrow. In fact, spinal epidural needles aren't even used to aspire to start with – they are used only to inject anaesthetic substances. It is

Applicant's position that one of ordinary skill in the art would not have viewed the structural attributes of a needle used only for injection liquids in soft tissue, and contemplated utilizing the structure for a device structured to penetrate hard tissue (bone cortex) and subsequently *withdraw* bone marrow from within bone. The Examiner has failed to provide a motivation to support a proper rejection on obviousness grounds. Even more untenable is the Examiner's assertion that one of ordinary skill would have transferred a spinal epidural needle technique in spinal tissue to procedural steps relevant to bone tissue.

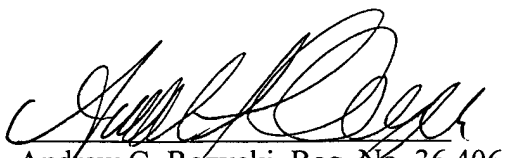
Given the above in addition to Applicant's arguments set forth in the previous response mailed November 4, 2004, the claimed invention is not unpatentable in view of the Krueger and Pyles references within the proper meaning of 35 U.S.C. §103. This rejection should, therefore, be withdrawn.

Conclusion:

In light of the above amendments and the accompanying remarks, it is believed that the application is now in condition for allowance, and prompt notification to that effect is earnestly solicited. The Examiner is invited to contact the undersigned to discuss the application on the merits if it is believed that such discussion would expedite the prosecution.

Respectfully submitted,

Dated: 4/5/05


Andrew G. Rozycki, Reg. No. 36,406
Attorney for Applicants
Cardinal Health, Inc.

7000 Cardinal Place
Dublin, Ohio 43017
Tel. (614) 757-7413
Fax (614) 757-2243